

APPENDIX D

APPLICATION OF APPLICANTS' CLAIMS TO THE '815 PATENT

Appln. No. 08/236,402

Claims

34. A peptide comprising

U.S. Patent No. 5,443,815

Column 3, lines 18-20: The peptides . . . are comprised of between 4 and 100 amino acid residues covalently linked to a radioisotope complexing group . . .

a biological-function domain which causes the peptide to localize at a target site, and

Column 3, lines 38-40: The invention encompasses peptides for labeling with Tc-99m and imaging target sites within a mammalian body . . .

Column 2, lines 24-26: [T]he specific binding of the radioactive peptide concentrates the radioactive signal over the cells of interest . . .

a metal ion-binding domain

Column 3, lines 24-25: radioisotope complexing group

Column 9, line 5: radiolabel complexing moiety.

which comprises the sequence Gly-Gly-Z or Gly-Gly-Gly-Z wherein Z is selected from the group consisting of cysteine, homocysteine, isocysteine, penicillamine, 2-mercaptoethylamine, 3-mercaptopropylamine

Table I: SEQ.ID.NO.:2: ...Gly-Gly-Cys.

Column 3, lines 25-33: Z is included in the structural formula where A is H or COOH, B is NH₂, X is SH, each of R and R¹ is H or CH₃ and n=0 or 1

and D-stereoisomers thereof.

Column 3, lines 25-33: The structural formula includes all stereoisomers of Z. Glycine has no asymmetric carbon atom.

35. A peptide according to claim 34 in which the metal ion-binding domain further comprises a radioactive metal ion coupled thereto.

Column 3, lines 53-58: The present invention provides Tc-99m labeled peptides for imaging target sites within a mammalian body that comprise between 4 and 100 amino acid residues and are covalently linked to a radioisotope complexing group wherein the complexing group binds a radioisotope.

36. A method for radiolabeling a peptide which comprises the steps of

(a) reacting

Column 4, lines 12-15: In forming a complex of radioactive technetium with the peptides of this invention, the technetium complex, preferably a salt of Tc-99m pertechnetate, is reacted with the peptides of this invention . . .

a peptide comprising a biological function domain which causes said peptide to localize at a target site, and a metal ion-binding domain which comprises the sequence Gly-Gly-Z or Gly-Gly-Gly-Z wherein Z is selected from the group consisting of cysteine, homocysteine, isocysteine, penicillamine, 2-mercaptoethylamine, 3-mercaptopropylamine and D-stereoisomers thereof with Tc-99m ion, and (b) recovering radiolabeled peptide.

As in Claim 34

*See Column 4, lines 12-15, quoted above
inherent*

37. A method of detecting at least one of the existence and locus of infection or inflammation in the body of a mammalian subject suspected of suffering from infection or inflammation, the method comprising:

- (a) administering to said subject

Column 5, lines 13-25: Technetium-labeled peptides provided by the present invention can be used for visualizing organs such as the kidney for diagnosing disorders in these organs, and tumors, such as gastrointestinal tumors, myelomas, small cell lung carcinoma and other APUDomas, endocrine tumors such as medullary thyroid carcinomas and pituitary tumors, brain tumors such as meningiomas and astrocytomas, and tumors of the prostate, breast, colon, and ovaries can also be imaged. In accordance with this invention, the technetium-labeled peptides or anionic complexes either as a complex or as a salt with a pharmaceutically acceptable cation are administered in a single unit injectable dose.

a peptide comprising a biological-function domain which causes the peptide to localize at a target site, and a metal ion-binding domain which comprises the sequence Gly-Gly-Gly-Z or Gly-Gly-Gly-Z wherein Z is selected from the group consisting of cysteine, homocysteine, isocysteine, penicillamine, 2-mercaptoethylamine, 3-mercaptopropylamine and D-stereoisomers thereof,

As in Claim 34

said peptide bearing a Tc-99m ion which has been coupled to said metal ion-binding domain; and

As in Claim 35

(b) detecting the Tc-99m bearing peptide, and thereby determining the existence and locus of infection or inflammation.

See column 5, lines 13-25, as quoted above